An Evaluation of Medication Adherence and Self-Management Techniques in Patients with Epilepsy

Submitted as part of Linsey McFadden's Undergraduate Honors Thesis

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Abstract

BACKGROUND: Comprehensive treatment of epilepsy involves many facets including self-management behaviors. The most common self-management strategy is adherence to an Antiepileptic Drug (AED) regimen. Controlling other non-drug related factors, such as management of information, concern for personal safety, management of the seizures themselves, and lifestyle issues may play an equal or greater role in the overall success of epilepsy therapy than does adherence to patients' medication regimen. The purpose of this study was to determine the relationship between the self-management behaviors and clinical outcomes.

METHODS: Adult epilepsy patients whom were able complete the surveys by themselves and had been taking AED therapy for at least 6 months were recruited from The Ohio State University Medical Center's outpatient epilepsy clinic for this cross-sectional, descriptive study. We used two previously-validated surveys to assess various self-management behaviors. Morisky's four-item self-reported adherence measure (not epilepsy-specific) and DiIorio's 38-item scale that assesses frequency of use of epilepsy self-management practices were administered to a convenience sample of patients. We also collected clinical (seizure activity, number of AEDs and presence or absence of toxicity) and demographic information. The response to the Morisky questions provides a score ranging from 1 to 4. A score of 0 or 1 categorizes the patient in the low medication-taking behavior group, a score of 2 or 3 is medium and 4 is high medication-taking behavior. On the Epilepsy Self-Management scale (ESMS), each item is rated on a 5-point scale ranging from 1=Never to 5=Always. Higher sores indicate more frequent use of self-management strategies. In addition, this scale can be divided into 5 subscales that address patient management of medication, information, safety, seizure and lifestyle. Patients were grouped into three categories based on their seizure frequency (seizure-free, <1 seizure per week and >1 seizure per week).

RESULTS: A sample of fifty-four patients were recruited from the Medical Center's Comprehensive Epilepsy Program. Of those patients, only 50 patients (23 women) provided adequate data for analysis. Their average age was 40.2 yrs (range 20-70). Their monthly seizure burden ranged from seizure-free (n=23) to "daily" seizures. Patients were taking an average of 1.64 AEDs (range 1-4) as well as other prescription medications (mean=4.05 ± 3.39). Most of the patients (n=34) reported no toxicity at their clinic visit. Based on their Morisky Score, patients fell into either the Low (n=2), Medium (n=27) or High (n=21) medication-taking behavior categories. The mean overall ESMS score was 3.72 ± 0.41. The ESMS subscale scores for patient management of medication, information, safety, seizure and lifestyle were 4.42, 2.65, 3.93, 4.00 and 2.62, respectively. The Morisky and ESMS medication management subscale scores correlated with each other. Medication taking behavior did not solely predict positive therapeutic outcomes. Patients scored the lowest on the information and lifestyle management subscale scores.

CONCLUSION: In our convenience sample of patients with epilepsy, we have found that self-management skills, beyond medication-taking behaviors, should be an area of emphasis during patient interactions.

Background

Much attention has been paid to medication adherence and its role in the therapeutic outcomes of patients with a variety of disease states. Though many different definitions of medication adherence are available, the term can be sufficiently defined as "the taking of prescribed medication at the correct times, in the correct dosage, remembering to take doses, and continuing to take the medication for the duration prescribed."[1] For many years, a body of evidence has accumulated showing a substantial percentage of patients who receive prescription medications fail to take their medications as prescribed. In a large segment of the patient population, missed doses and early cessation of therapy is the norm. As an example, studies have suggested that dropout rates for cholesterol-lowering medications may be as high as 50% after only 3 months of therapy.(ref)

It has been asserted that failure to comply with a prescribed medication regimen will have a negative effect on the outcome of treatment.[2] For example, adherence has been deemed crucial to the successful treatment of patients with hypertension.[3] Experience shows that the majority of the difficulty in maintaining blood pressure control is in patient adherence to medication plans over the long term. Even mild deviation from the prescribed medication schedule can produce a substantial drop-off in therapeutic success for this condition.

Epilepsy is a common neurological problem affecting 1-3% of the United States population. Epilepsy has significant economic and social consequences. These can be minimized by optimal seizure control.

Antiepileptic drugs are the mainstay of treatment in this chronic disease. Despite the fact that the number of antiepileptic drugs approved by the FDA has tripled over the last 10 years (see Figure below), it is estimated that 30% of patients with epilepsy are not controlled. Reasons for treatment failure include inappropriate drug selection, inappropriate dose, patients with resistant epilepsy and poor adherence. This project focuses on the latter.

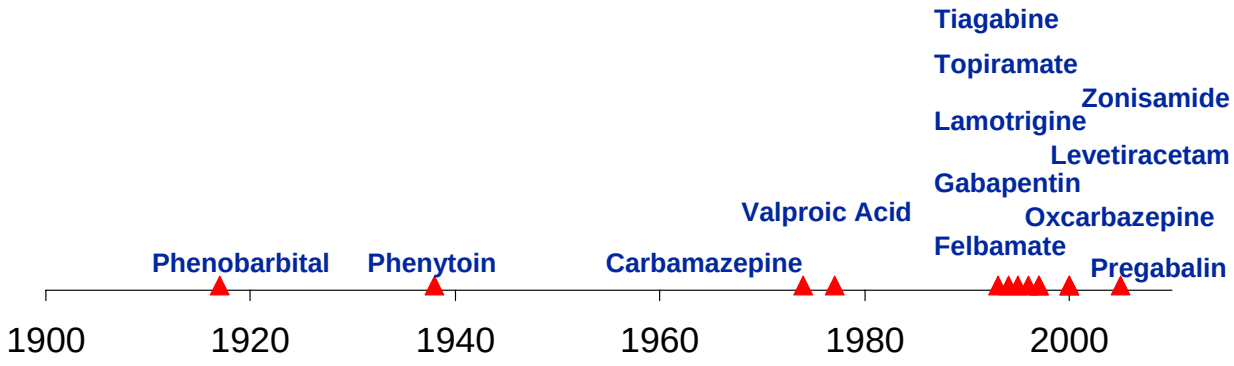

Figure 1. Timeline of when current Antiepileptic Drugs(AEDs) were marketed.

With regards to epilepsy, prior studies in this realm have shown an appreciable correlation between stated anti-epileptic drug (AED) adherence and resultant seizure control. Cereghino et al. were able to show that 80% of patients determined to be adherent through self-completed survey were able to achieve some modicum of seizure control with minimal adverse effects.[4] However Leppik and Schmidt concluded that 30-60% of patients with epilepsy were non-adherent with their AED medication regimens, thus depriving themselves of the opportunity for this optimal control.[5]

Comprehensive treatment of epilepsy by the patient involves many facets beyond medication; this is defined by Di Iorio et al as self-management.[6] A patient who is perfectly adherent with their AED regimen may still experience

seizure activity if they are negligent in maintaining good self-management habits. Failing to get adequate sleep, indulgence in excessive alcohol consumption or recreational drug use, or allowing stress to become too great are examples of common self-management lapses.

Though medication adherence is important in patient's with epilepsy, their diligence in controlling other non-drug related behavioral factors, such as management of information, concern for personal safety, management of the seizures themselves, and lifestyle issues may play an equal or greater role in the overall success of epilepsy therapy than adherence to their medication regimen. The purpose of this study was to determine the relationship between the self-management behaviors and clinical outcomes.

Methods

Study Details

This was a cross-sectional, descriptive study. It was approved by the OSU Institutional Review Board. Fifty-four patients in the Medical Center's Comprehensive Epilepsy clinic who met the inclusion criteria were recruited to complete the two surveys. This represented a convenient sample that allowed us to gather data to answer the relevant questions. After patients signed the consent and confidentiality forms, they were given the option to complete the surveys in the clinic or take them home with them and send them back via a pre-paid envelope. The surveys were administered one time and took 10-15 minutes to complete. Patients were given a $5 gift certificate to Bob Evans' Restaurants for their time in completing the surveys.

Inclusion criteria:

- Patients were able to provide consent and complete survey by themselves
- Patients were taking antiepileptic drug therapy for at least the past 6 months
- Patients had a clinical diagnosis of epilepsy and be at least 18 years of age

Instruments

In this project, we combined the surveys derived and utilized by Morisky and DiIorio to differentiate determinants of success in epilepsy therapy. These allowed us to assess the impact of self-management practices on clinical outcomes in patients with epilepsy.

Morisky et al. developed a brief, easily understood and valid survey to be administered to patients in the clinical setting. This survey was very successful in predicting positive therapeutic outcomes by identifying hypertensive patients with good medication adherence.[3] By linking the answers in their survey with the documented success or failure of the respective patients' therapy, the group was able to draw a solid correlation between survey response and predictable treatment outcome in patients on antihypertensive therapy. For our purposes, we have taken the four key adherence – oriented questions in the Morisky survey and added demographic information (Appendix A). Scores range from 0 to 4, with 4 depicting high medication-taking behavior and 0 depicting low. The patients answered these four questions either 'yes' or 'no'.

DiIorio has created a series of surveys to be utilized in the clinical setting in an attempt to determine AED adherence in patients with epilepsy and analyze the ability of a patient to manage their condition in areas other than their medication. One of these tools, the Epilepsy Self Management Scale (ESMS), is a survey comprised of 38 questions related to medication taking, safety precautions, and general self-management issues (Appendix B).[7] Each question in the survey is rated on a 5-point scale from *never* (1) to *always* (5). The higher the total score of the survey respondent, the better their self-management practices. The scale has been used in epilepsy self-management studies, with a reliability coefficient ranging from 0.81 to 0.84, indicating uniform consistency in results across and within sample groups.

In addition to the two surveys, key demographic and clinical information on each patient was gathered at the time of their clinic visit. The clinical data included number of AEDs, seizure activity over the last three months, details on current adverse events, and whether they were AED-resistant (previously-failed two AEDs).

Data Analysis

Data were collected and entered into an Excel spreadsheet. Descriptive statistics were done in Excel. The total number of patients recruited into the study was 54. Two of the patients never returned the survey via mail as promised. One survey was excluded because of too much missing data. After performing a Q test for rejection, the Q critical value was determined to be 0.640 which allowed for exclusion of this patient's data. A fourth patient was excluded at the time of analysis because of a questionable diagnosis of epilepsy. The total number of patients analyzed was 50. Patient's degree of therapeutic outcome was determined by their current seizure status due to the cross-sectional method of this study. Based on their seizure control over the past three months, they were divided into three categories: seizure free, less than 1 seizure per week, and more than 1 seizure per week.

Results

As can be seen from Table 1, there was an approximate 50% split between each of the genders surveyed. These patients ranged in age from 20 to 70 years old. Of the fifty patients, 46 of them were of Caucasian race. Almost half of the patients were currently seizure free at the time the survey was administered and about 30% were experiencing adverse events from their AEDs. The average total number of medications patients were on was 4 with good deal of variance. Approximately 1 to 2 of these drugs were determined to be for epilepsy.

Number (Men/Women)	50 (27/23)
Mean Age (range)	40.20 yrs (20 – 70)
Ethnicity	46 White, 3 Black, 1 Other
Seizure-Free Patients	23
Mean # Antiepileptic Drugs	1.64 ± 0.83
Mean # Total Meds	4.05 ± 3.39
AED_resistant patients	35 of 50
Adverse Events Present	16 of 50

Table 1. Patient Demographics

Figure 2 is a breakdown of the average scores on the 38 ESMS questions and placed into the 5 subscales DiIorio allotted. We added some of the unidentified questions by DiIorio that reasonably fit into the original medication management subscale, thus the asterisks on the Meds subscale. The medication management* subscale had the highest average score, while the other four subscales (information, safety, seizure, and lifestyle) showed lower average scores in this patient population.

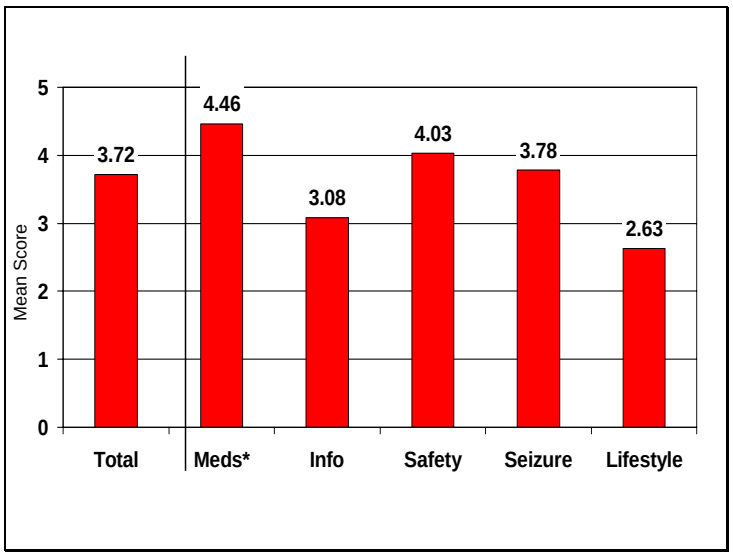

Figure 2. ESMS Total & Subscale Scores

In Figure 3 below, survey participants were classified into low, medium, and high medication adherence categories according to their responses in the Morisky scale, and then compared to the ESMS (MM*). It shows a direct correlation between the two scales, Morisky's and MM*, which both aimed to measure medication adherence. This validates that we were indeed measuring what we intended to measure with our survey utilizing two scales.

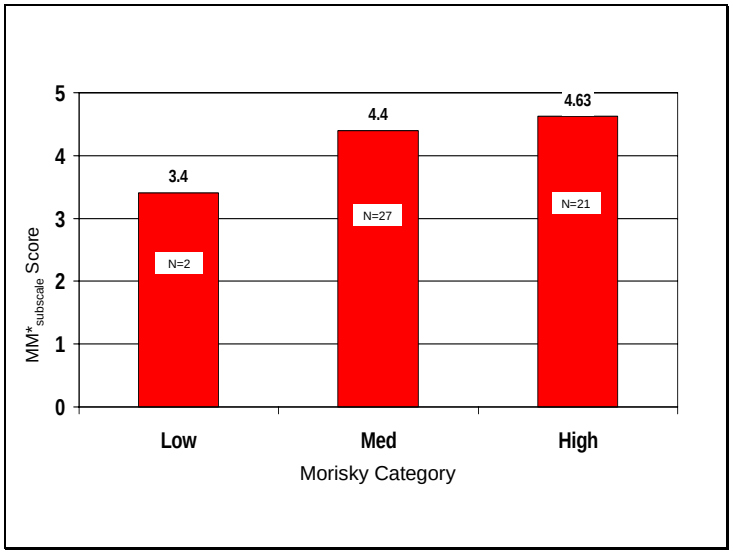

Figure 3. Morisky & $ESMS_{MM}$* Correlation

The fourth figure below shows the relationship between medication management and seizure status. In the Morisky scale, there is a trend showing that as seizure burden increased, the patients' medication management scores decreased. This is what one would expect to see. This relationship was not seen with the ESMS subscale. This gives us reason to believe that there are indeed other factors in predicting seizure status, not solely medication adherence.

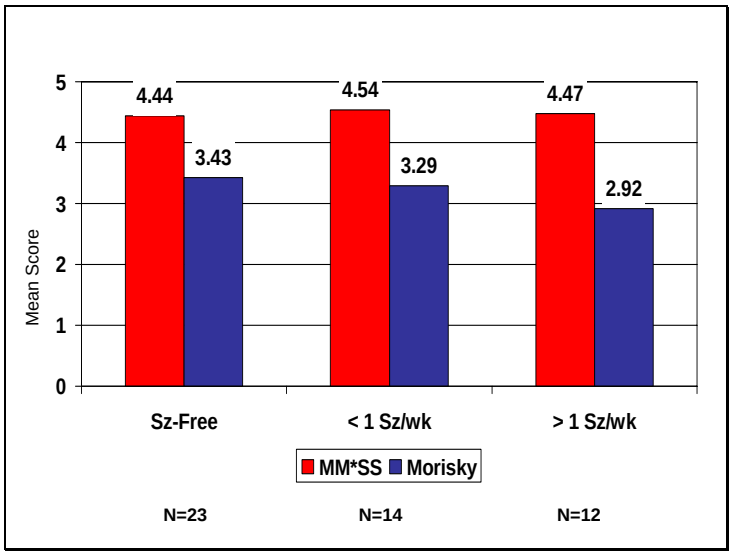

Figure 4. Relationship between Medication Taking Behavior and Seizure Status

In Figure 5 below, the relationship between safety and information management versus seizure status is actually quite interesting. This information was not what we expected to see, but we found possible reasoning as to why patients may behave in the manner we found. We seemed to notice a slight increase in self-management scores along the x-axis as seizure burden increased. We interpret this data to mean that those patients having many seizures per week must try to incorporate more safety as well as information precautions and sources respectively in their everyday lives as compared to the seizure-free patients who may be less concerned due to their stable condition. In

contrast, the seizure and lifestyle management subscales showed very little variance between each seizure status category and without any apparent trend. Therefore, the relationship between these subscales and seizure status was found to be indeterminable until perhaps further detailed analyses can be completed.

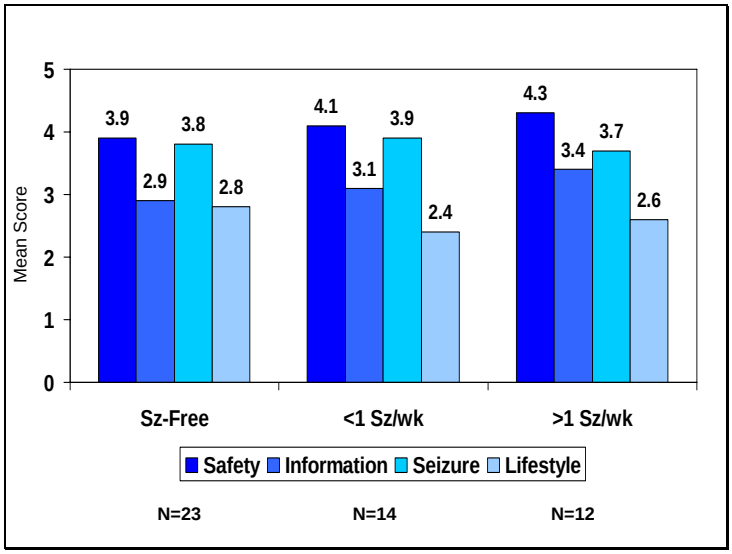

Figure 5. Relationship between Subscales and Seizure Status

Discussion

This project is the first to attempt to identify the impact of self-management behaviors on clinical outcomes in patients with epilepsy.

We have learned that in the clinic, health care providers should stress the importance of a patient adhering to a medication regimen. Though it is clinical practice to do such reinforcement of medication adherence, this study highlights that other factors should not be ignored. Our data show where patients' weaknesses lie and therefore they may benefit from increased counseling in these other areas. In particular, *lifestyle* management was consistently the lowest scoring region of self-management techniques in patients. This can be improved by informing patients that getting enough sleep, exercising regularly, eating regular meals, and doing things such as relaxation, guided imagery, and self hypnosis to manage stress can all be ways to help manage seizures.

Techniques from the other low scoring categories may also be touched upon in the clinical setting which could lead to improvement in a patients' seizure status. From the *information* management category, the following types of advice could be given: keep record of when seizures occur and the types of side effects present, call the doctor when problems arise, have blood tests performed regularly, attend all clinic appointments, participate in an epilepsy support group, and carry identification of medical conditions

To score higher in the *safety* management area, patients may be advised to avoid many alcoholic beverages, keep temperatures constant in the home, check with a doctor before taking other medications, refrain from late nights out, take showers instead of baths, never go swimming alone, never use power tools without an automatic shutoff, and avoid climbing high stools, chairs, and ladders. These suggestions may prevent harmful or fatal accidents from occurring if a seizure were to occur during such an event.

It is important to point out a few of the limitations present in this study of medication adherence and self-management techniques. First of all, the sample size of 50 is a relatively small number, especially considering the fact that we further broke down the population into various smaller categories in analysis. Additionally, this relatively small sample size is rather heterogeneous with regard to age, seizure control and AED resistance. We also realize that we could have gathered other key demographic data, such as socioeconomic status. A fourth limitation to consider is that the study is a cross-sectional design in which we did not return to the patients at a later date to assess improvements or delays in seizure status or management. Lastly, there is a chance that non-adherence may have been under-reported due to the self-assessment nature of the survey.

Ongoing analysis using more sophisticated techniques is planned and may provide additional insight.

In conclusion, in our convenience sample of patients with epilepsy, we have found that self-management skills, beyond medication-taking behaviors, should be an area of emphasis during patient interactions.

References

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APPENDIX A. Demographic Data Collection Form and Morisky Medication-Taking Behavior Survey

DO NOT PUT YOUR NAME ON THIS SURVEY

Medication Questionnaire

Instructions: Please answer all of the questions as best as you can. Participation is fully optional. Results from this survey will be used to develop educational materials to help patients use their medicines more effectively. Thank you for your participation.

1. How old are you? ☐☐ years (fill in the blank)

2. Gender ○ Male ○ Female (Select one)

3. How many years of school did you finish? (Select one)

○ 8th grade or less
○ High school or GED
○ Some college
○ College graduate

4. How many prescription medications do you take each day? ☐☐ (fill in the number)

5. For which of the following medical conditions do you take medicine prescribed by your doctor? (you may select more than one)

○ High blood pressure	○ Diabetes
○ Stroke	○ Ulcer of the stomach or intestine
○ Heart attack	○ Heartburn (also called reflux)
○ High cholesterol	○ Arthritis
○ Depression	○ Asthma, emphysema or other breathing problems
○ Anxiety (nerve problems)	○ Cancer
○ Seizures/epilepsy	○ Allergy

Morisky Medication-Taking Behavior Questions

6. Do you ever forget to take your medications?
○ Yes ○ No (Select one)

7. Are you careless (not concerned) at times about taking your medications?
○ Yes ○ No (Select one)

8. When you feel better, do you sometimes stop taking your medications?
○ Yes ○ No (Select one)

9. Sometimes if you feel worse when you take a medicine, do you stop taking it?
○ Yes ○ No (Select one)

10. Do you ever skip doses or take less medicine to save money?
○ Yes ○ No (Select one)

11. How do you rate your current health status? (Select one)

○ Very Poor
○ Poor
○ Fair
○ Well
○ Very Well

Thank You

Do not write in this area
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APPENDIX B. DiIorio's Epilepsy Self-Management Scale [ESMS]

Epilepsy Self Management

Instructions: The following statements describe what people do to manage their epilepsy. Please fill-in a circle for each statement to show how often you do the following. As you answer the questions, please think about your activities in the past year.

	Never	Rarely	Sometimes	Most of the time	Always
1. I write down how often I have seizures and when they occur.	○	○	○	○	○
2. I do things such as relaxation, guided imagery, and self hypnosis to manage stress.	○	○	○	○	○
3. I call my doctor when I think I am having side effects from my seizure medications.	○	○	○	○	○
4. When my seizure medication is running out, I spread out the time between doses.	○	○	○	○	○
5. I keep a record of the types of seizures I have.	○	○	○	○	○
6. I stay out late at night.	○	○	○	○	○
7. I keep track of the side effects of my seizure medications.	○	○	○	○	○
8. When my seizure medication is running out, I take less medication at each time.	○	○	○	○	○
9. I take my seizure medication the way my doctor orders it.	○	○	○	○	○
10. I stay out of situations that might cause a seizure.	○	○	○	○	○
11. If I am going away from home, I take my seizure medication with me.	○	○	○	○	○
12. I call my doctor if I am having more seizures than usual.	○	○	○	○	○
13. I make sure I get enough sleep.	○	○	○	○	○
14. I do things that I enjoy to help manage stress.	○	○	○	○	○
15. I have a way to remind myself to take my seizure medications.	○	○	○	○	○
16. I take my seizure medications at the same time each day.	○	○	○	○	○
17. I would go swimming alone.	○	○	○	○	○
18. I do things such as relaxation, guided imagery, and self hypnosis to keep myself from having a seizure.	○	○	○	○	○
19. When the doctor orders blood tests, I have them done.	○	○	○	○	○

Continued

	Never	Rarely	Sometimes	Most of the time	Always
20. I wear or carry information stating that I have epilepsy.	○	○	○	○	○
21. I have to put off having my seizure medication refilled because it costs too much money.	○	○	○	○	○
22. I get enough exercise.	○	○	○	○	○
23. I use power tools such as electric saws, electric hedge trimmers, or electric knives without an automatic shutoff.	○	○	○	○	○
24. I miss doctor or clinic appointments.	○	○	○	○	○
25. If I had side effects from the seizure medications, I would skip a dose without asking my doctor.	○	○	○	○	○
26. I take showers instead of baths.	○	○	○	○	○
27. I plan ahead and have my seizure medication refilled before I run out.	○	○	○	○	○
28. I miss doses of my seizure medication because I do not remember to take it.	○	○	○	○	○
29. I keep the temperature of the water in my home low enough so I do not get burned.	○	○	○	○	○
30. I skip doses of seizure medication.	○	○	○	○	○
31. I check with my doctor before taking other medicines.	○	○	○	○	○
32. I stay away from things that make me have seizures.	○	○	○	○	○
33. I eat regular meals.	○	○	○	○	○
34. I climb objects such as high stools, chairs, or ladders.	○	○	○	○	○
35. I talk with other people who have epilepsy.	○	○	○	○	○
36. I drink a lot of alcoholic beverages such as beer, wine, and whiskey.	○	○	○	○	○
37. I participate in a support group for person with epilepsy.	○	○	○	○	○
38. I practice what to do during a seizure with my family and friends.	○	○	○	○	○

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